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EXHIBIT 2

510(k) Summary

Meridian Co., Ltd..
4Fl., Hongsung Bldg. 197-3 Jamsil-Dong, Songpa-Gu, Seoul
138-220 Korea
Phone: 82-2-2103-3300
Fax: 82-2-2103-3333

November 22, 2004

Contact: Soorang Lee, R&D Director

1. **Identification of the Device:**
   Proprietary-Trade Name: Lapex 2000
   Classification Name: Lamp, non-heating, for adjunctive use in pain therapy NHN
   Common/Usual Name: Infrared Lamp

2. **Equivalent legally marketed devices** LAPEX-2000 is substantially equivalent to other low level therapeutic lasers currently in commercial distribution. These predicate devices include THOR International Ltd. THOR DDII 830CL3 Laser System (K030226),and the MicroLight 830 (K010175). The LAPEX-2000 has same intended use as and similar technological characteristics to these predicate devices.

3. **Indications for Use (intended use)** The LAPEX-2000 is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.

4. **Description of the Device:** The LAPEX-2000 is a low level laser therapy device.

Semiconductor Laser Therapy System	▪ Non-invasive digital semiconductor laser therapy
Safe treatment	▪ Non-invasive therapy type ▪ Non-painful & security therapy for a patient
Light and portable	▪ A small volume by using semiconductor laser diodes ▪ Easy operation and portable
User friendly operation	▪ Therapy information display on LCD monitor ▪ Easy key operation

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices.

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6. Substantial Equivalence Chart

Feature	LAPEX-2000	Predicates	
		THOR DDII 830CL3 Laser System (K030226)	MicroLight 830, (K010175)
PROBE			
Source	Diode GaAlAs	Diode GaAlAs	Diode GaAlAs
Type	Continuous & Modulated Continuous	Continuous & Modulated Continuous	Continuous & Modulated Continuous
Wavelength	830nm	830nm	830nm
Output Power	30mW x 3	30mW x 3	30mW x 3
Intended use	The LAPEX-2000 is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.	The THOR DDII 830CL3 Laser System is non-Heating infrared lamp and is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with carpal tunnel syndrome	Adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome

7. Conclusion

After analyzing bench, electrical safety, EMC, and user testing data, it is the conclusion of Meridian Co. Ltd.. that the Lapex 2000 is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 1 2005

Meridian Company, Ltd.
c/o Mr. Daniel Kamm, P.E.
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K034009
Trade/Device Name: Lapex 2000
Regulation Number: 21 CFR 890.5500
Regulation Name: Lamp, non-heating for adjunctive use in pain therapy
Regulatory Class: II
Product Code: NHN
Dated: November 22, 2004
Received: November 23, 2004

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K034009

Device Name:

Indications For Use: The LAPEX-2000 is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K034009